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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,867	02/04/2002	Halle Morton	999710000008	3108

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EXAMINER	
ANDRES, JANET L	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,867	MORTON ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *12-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 February 2005 has been entered. Claims 1-25 are pending in this office action. Claims 12-24 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Maintained

2. The rejection of claims 1-11 under 35 U.S.C. 103(a) as unpatentable over Morton et al. in view of the M.S. study is maintained for reasons of record in the office actions of 5 August 2003 and 5 October 2004 and applied to new claim 25.

Applicant has amended claim 1 to require sub-optimal amounts of cpn 10 and IFN-β. Applicant argues that the combined references do not teach co-operative reduction of symptoms or a delay in MS relapse. Applicant further argues that the teachings of individual effectiveness do not suggest that the combination of the two agents would produce a therapeutic effect.

Applicant's arguments have been fully considered but have not been found to be persuasive.

While Applicant is correct in the statement that the prior art does not teach co-administration of suboptimal levels of the two agents, the levels specified in the dependent

claims are within the ranges taught by the prior art. As stated in the office action of 5 August 2003, Morton et al. teaches a range of .07 -70 mg of cpn 10 in humans. The M.S. study teaches that 1.6 and 8 MIU of IFN-β are both effective. Thus, what is claimed is not "suboptimal" but is a combination of the ranges taught by the prior art. Claim 25 has no requirement that the levels be suboptimal. Thus the claims do not differentiate over what is rendered obvious by the prior art. While Applicant argues that the prior art does not teach a co-operative reduction or delay in relapse, such would inherently result from the co-administration of the levels taught in the prior art. Applicant cites *Gillette* and *in re Eli Lilly* and concludes that the fact that the treatments are individually effective would not lead the artisan to conclude that they would b effective together. However, Applicant does not explain why two agents known to work in the prior art would not be expected to work when combined. This is not an "obvious to try" standard. Each of the agents is functional on its own. While Applicant argues that "very distinct" differences are observed, the artisan would expect that two agents would work better than one if they were merely additive in their effects. Table 4 does not appear to directly compare the combined treatment to each alone, but the levels do not appear to be significantly different, nor has Applicant provided any evidence that advantages would occur from the administration of "suboptimal" levels, since results were observed from each compound administered alone.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-7 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of M.S. using cpn 10 and IFN-β, does not reasonably provide enablement for treatment using suboptimal levels. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman,* (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands,* 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Both the specification and the prior art teach that IFN-β and cpn 10 can be used to treat M.S. However, the claims require that levels that are less than optimally effective alone be used. There is no guidance in the specification to indicate that such treatment would be successful. According to table 3, the amount of cpn 10 used was as effective as higher doses and thus was not "suboptimal". The examiner is unable to find a comparison of levels of IFN-β in the specification. However, based on table 4, the level of IFN-β was sufficient to cause an effect. Thus, it would require further guidance for the artisan to predictably be able to determine and successfully administer suboptimal levels of these two compounds.

4. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 2 is drawn to prevention of relapse. What appears to be shown is a decrease in the symptoms associated with relapse. To the examiner's knowledge MS is not curable and thus "prevention" is not enabled.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are indefinite in the recitation of "suboptimal". Neither optimal nor suboptimal levels are defined in the specification and the artisan would be unable to determine what levels Applicant intended the claims to encompass.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
25 April 2005

JANET ANDRES
PRIMARY EXAMINER